DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDAs 19-781/S-005, 006
20-843/S-005, 006

Unimed Pharmaceuticals, Inc.
Attention: Joyce Armstrong
901 Sawyer Rd.
Marietta, GA 30062

Dear Ms. Armstrong:

Please refer to your supplemental new drug applications dated December 12, 2000 received December 13, 2000 (S-005), and January 11, 2001 received January 12, 2001 (S-006), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PROMETRIUM® (progesterone, USP) Capsules.

We acknowledge receipt of your submissions dated August 18 (NDA 19-781/005, 006), October 11, November 10 and December 1, 2004.

These "Changes Being Effected in 30 Days" supplemental new drug applications provide for revisions to the patient package insert that include updated safety information based on post-marketing experience and changes to update the labeling regarding the Women's Health Initiative Memory Study (WHIMS).

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDAs 19-781/S-005, 006 and 20-843/S-005, 006." Approval of these submissions by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Kassandra Sherrod, R.Ph., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Daniel A. Shames

12/10/04 01:03:04 PM